

Amendments to the Specification

Please replace the TITLE with the following amended TITLE:

~~DEVICES AND METHODS FOR IMPROVING VISION~~ INSERTING LENSES INTO
CORNEAL EPITHELIAL POCKETS TO IMPROVE VISION

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1-80. (Cancelled)

81. (Currently amended) A method for vision correction, comprising:

inserting a lens into a pocket created between a corneal epithelium of an eye and Bowman's membrane of the eye.

~~inserting a vision correcting ocular device beneath an epithelium of a cornea of an eye substantially without uncovering an anterior surface of the cornea located under the epithelium.~~

82. (Currently amended) The method of claim 81, further comprising forming an incision in the epithelium to create the pocket, and inserting the ocular device through the incision.

83. (Original) The method of claim 82, wherein the step of forming an incision includes forming an incision on an approximate nasal portion, a temporal portion, a superior portion, and/or inferior portion of the epithelium.

84. (Currently amended) The method of claim 82, wherein the step of forming an incision includes forming an incision on an approximate medial portion of the epithelium to form a first pocket and a second pocket, each pocket sized to accommodate a portion of the lens body.

85. (Currently amended) The method of claim 81, further comprising deforming the ocular device lens prior to the inserting step.

86. (Currently amended) The method of claim 81, further comprising removing the ocular device lens from the eye, and inserting another vision correcting ocular device ~~beneath the epithelium of the eye~~ lens into the pocket.

87-88. (Cancelled)

89. (Currently amended) The method of claim 81, wherein the ocular device ~~lens~~ comprises a synthetic material.

90. (Currently amended) The method of claim 81, wherein the ~~ocular device~~ lens comprises a synthetic polymeric material.

91. (Original) The method of claim 81, wherein the inserting step occurs without forming an epithelial flap.

92. (Original) The method of claim 81, further comprising forming a plurality of incisions in the epithelium.

93. (Cancelled)

94. (Currently amended) The method of ~~claim 93~~ claim 81, wherein the inserting step occurs substantially without damaging Bowman's membrane ~~a Bowman's membrane of the cornea~~.

95. (Currently amended) The method of ~~claim 93~~ claim 81, wherein the inserting step occurs substantially without damaging a portion of a stroma of the cornea of the eye.

96. (Original) The method of claim 81, further comprising administering a healing agent to the eye in an amount effective to promote healing of the epithelium.

97. (Currently amended) The method of claim 81, wherein the inserting step comprises lifting a portion of the epithelium from the cornea, forming an incision in the epithelium, and passing the ~~ocular device~~ lens through the incision.

98. (Original) The method of claim 97, wherein the epithelium is lifted using a vacuum.

99. (Original) The method of claim 97, wherein the epithelium is lifted by delivering a fluid beneath the epithelium.

100. (Original) The method of claim 81, further comprising applying an effective amount of an epithelium preserving agent to the epithelium.

101. (Original) The method of claim 100, wherein the epithelium preserving agent includes a gel.

102. (Original) The method of claim 100 wherein the epithelium preserving agent comprises a component selected from the group consisting of water soluble polymeric materials, water swellable polymeric materials and mixtures thereof.

103. (Original) The method of claim 100, wherein the epithelium preserving agent includes at least one cellulosic component.

104. (Original) The method of claim 103, wherein the epithelium preserving agent includes hydroxymethylcellulose.

105. (Currently amended) The method of ~~claim 82~~ claim 81, ~~wherein forming step comprises further comprising creating the pocket~~ using a sharp blade to slice through the epithelium.

106. (Currently amended) The method of ~~claim 82~~ claim 81, ~~wherein the forming step comprises further comprising creating the pocket~~ using a blunt instrument to separate the epithelium substantially without slicing the epithelium.

107. (Currently amended) The method of ~~claim 82~~ claim 81, wherein the ~~forming creating~~ step comprises using a microkeratome.

108. (Original) The method of claim 106, wherein the blunt instrument is a spatula or a wire.

109-111. (Cancelled).

112. (Previously presented) The method of claim 99, wherein the fluid includes sodium chloride and/or other tonicity agent.

113. (Previously presented) The method of claim 99, wherein the fluid is a hypertonic aqueous liquid.

114-120. (Cancelled)

121. (Currently amended) The method of claim 81, further comprising:
applying a liquid to the ~~epithelium of a cornea of an eye~~ corneal epithelium, the liquid being effective in loosening the epithelium substantially without killing epithelial cells;
treating the epithelium to provide and/or maintain the epithelium in a moisturized state;

raising a portion of the loosened, moisturized epithelium from a surface of a cornea of an eye located below the epithelium;

separating the raised portion of the epithelium from the surface of the cornea;

forming one or more incisions in the raised portion of the epithelium to accommodate the ~~ocular device~~ lens.

122. (Original) The method of claim 121, wherein the steps occur sequentially.

123. (Currently amended) The method of claim 121, further comprising, prior to the forming step, delivering a substance beneath the raised portion of the corneal epithelium to

maintain a spaced apart relationship between the epithelium and Bowman's membrane ~~the surface of the cornea.~~

124. (Original) The method of claim 121, wherein the liquid that is applied includes sodium chloride and/or other tonicity agent.

125. (Original) The method of claim 121 wherein the liquid that is applied is a hypertonic aqueous liquid.

126. (Original) The method of claim 121, further comprising scoring a portion of the epithelium to create an epithelial defect prior to applying the liquid.

127. (Original) The method of claim 121, wherein the treating step comprises applying a gel to the epithelium.

128. (Original) The method of claim 127, wherein the gel-containing composition comprises a component selected from the group consisting of water soluble polymeric materials, water swellable polymeric materials and mixtures thereof.

129. (Original) The method of claim 127, wherein the gel-containing composition comprises at least one cellulosic component.

130. (Original) The method of claim 129 wherein the gel-containing composition comprises hydroxymethylcellulose.

131. (Cancelled)

132. (Original) The method of claim 121, wherein the step of separating the epithelium from the surface of the cornea includes using a blunt dissection apparatus.

133. (Cancelled)

134. (Original) The method of claim 121, wherein the substance that is delivered to beneath the raised portion of the epithelium is a gel-containing composition.

135. (Original) The method of claim 134, wherein the gel-containing composition comprises a component selected from the group consisting of water soluble polymeric materials, water swellable polymeric materials and mixtures thereof.

136. (Original) The method of claim 134, wherein the gel-containing composition comprises a cellulosic component

137. (Original) The method of claim 134, wherein the gel-containing composition includes hydroxymethylcellulose.

138. (Cancelled)

139. (Cancelled)

140. (Original) The method of claim 121, wherein the forming step comprises forming a plurality of incisions in the raised portion of the epithelium.

141-149. (Cancelled)

150. (Previously presented) The method of claim 81, further comprising administering a moisturizer to the epithelium effective in providing and/or maintaining the epithelium in a moisturized state.

151-159. (Cancelled)

160. (Currently amended) The method of claim 81, further comprising:
applying a liquid to the ~~epithelium of a cornea of an eye~~ corneal epithelium, the liquid being effective in loosening the epithelium substantially without killing epithelial cells;
raising a portion of the loosened epithelium from a surface of a cornea of an eye located below the epithelium;
separating the raised portion of the epithelium from the surface of the cornea;
delivering a substance beneath the raised portion of the epithelium to maintain a spaced apart relationship between the epithelium and the surface of the cornea;
forming one or more elongated incisions in the raised portion of the epithelium to accommodate the ~~ocular device~~ lens.

161. (Original) The method of claim 160, wherein the liquid that is applied includes sodium chloride and/or other tonicity agent.

162. (Original) The method of claim 160, wherein the liquid that is applied is a hypertonic aqueous liquid.

163. (Original) The method of claim 160, further comprising scoring a portion of the epithelium to create an epithelial defect prior to applying the liquid.

164. (Original) The method of claim 160, wherein the step of raising a portion of the epithelium includes using a vacuum.

165. (Original) The method of claim 160, wherein the step of separating the epithelium from the surface of the cornea includes using a blunt dissection apparatus.

166. (Original) The method of claim 165, wherein the blunt dissection apparatus comprises a spatula or a wire.

167. (Original) The method of claim 160, wherein the substance that is delivered to beneath the raised portion of the epithelium is a gel-containing composition.

168. (Original) The method of claim 167, wherein the gel-containing composition comprises a component selected from the group consisting of water soluble polymeric materials, water swellable polymeric materials and mixtures thereof.

169. (Original) The method of claim 167, wherein the gel-containing composition comprises at least one cellulosic component.

170. (Original) The method of claim 169, wherein the gel-containing composition includes hydroxymethylcellulose.

171. (Original) The method of claim 160, wherein the one or more incisions are formed using a microkeratome.

172. (Cancelled)

173. (Original) The method of claim 160, wherein the forming step comprises forming a plurality of incisions in the raised portion of the epithelium.

174-176. (Cancelled)

177. (Original) The method of claim 160, further comprising applying a healing agent to the epithelium at the one or more incisions.

178. (New) The method of claim 81, further comprising applying an aqueous fluid to the eye.

179. (New) The method of claim 178, wherein the aqueous fluid is selected from the group consisting of water and saline.

180. (New) The method of claim 178, further comprising cooling the corneal epithelium.

181. (New) The method of claim 81, further comprising securing the lens in the eye with an adhesive.

182. (New) The method of claim 181, wherein the adhesive is a biodegradable glue.

183. (New) The method of claim 81, wherein the lens comprises a cellular attachment element.

184. (New) The method of claim 81, wherein the lens comprises an agent selected from the group consisting of growth factors, extracellular matrix proteins, fragments thereof, and combinations thereof.

185. (New) The method of claim 81, wherein the lens comprises collagen.
186. (New) The method of claim 81, wherein the lens comprises recombinant collagen.
187. (New) The method of claim 81, wherein the lens comprises collagen and a synthetic polymeric material.
188. (New) The method of claim 81, wherein the lens is free of donor corneal tissue.
189. (New) The method of claim 81, wherein the lens comprises collagen Type I.
190. (New) The method of claim 81, wherein the lens comprises collagen other than collagen Type I.
191. (New) The method of claim 81, further comprising forming a blister that includes the corneal epithelium.
192. (New) The method of claim 191, wherein the forming step comprises applying a fluid to the corneal epithelium.
193. (New) The method of claim 191, wherein the forming step comprises applying a chemical to the corneal epithelium.
194. (New) A method for vision correction, comprising:
cooling a corneal epithelium of an eye; and
inserting a lens into a pocket created between the corneal epithelium and Bowman's membrane of the eye.
195. (New) The method of claim 194, wherein the cooling is effective in protecting corneal epithelial cells of the corneal epithelium from cellular injury resulting from creation of the pocket.
196. (New) The method of claim 194, wherein the pocket is created using a separator, and the separator is cooled to cool the corneal epithelium.
197. (New) The method of claim 194, further comprising applying an aqueous liquid to the eye.
198. (New) The method of claim 197, wherein the aqueous liquid is selected from the group consisting of water and saline.
199. (New) The method of claim 194, further comprising securing the lens to the eye with an adhesive.
200. (New) The method of claim 199, wherein the adhesive is a biodegradable glue.

201. (New) The method of claim 194, further comprising forming a blister that comprises the corneal epithelium.

202. (New) The method of claim 194, wherein the lens comprises collagen.

203. (New) The method of claim 194, wherein the lens comprises recombinant collagen.

204. (New) The method of claim 194, wherein the lens comprises a synthetic polymeric material.

205. (New) The method of claim 194, wherein the lens comprises collagen and a synthetic polymeric material.

206. (New) The method of claim 194, wherein the lens is free of donor corneal tissue.

207. (New) The method of claim 194, wherein the lens comprises collagen Type I.

208. (New) The method of claim 194, wherein the lens comprises collagen other than collagen Type I.

209. (New) The method of claim 194, wherein the lens comprises a cellular attachment element.

210. (New) The method of claim 194, wherein the lens comprises an agent selected from the group consisting of growth factors, extracellular matrix proteins, fragments thereof, and combinations thereof.

211. (New) The method of claim 194, further comprising creating the pocket using a microkeratome.

Amendments to the Abstract

Please replace the ABSTRACT with the following amended ABSTRACT:

Methods of correcting vision are described. The methods include inserting a lens into a corneal epithelial pocket or a pocket created between a corneal epithelium of an eye of a patient and Bowman's membrane of the eye. A lens is inserted into the pocket to correct vision. Certain methods include one or more steps of cooling the corneal epithelium, and applying an aqueous liquid to the eye. The lenses that are inserted into the pocket can include collagen, including recombinant collagen, synthetic polymeric materials, and combinations thereof.

~~A corneal appliance that is placed over an eye has a lens body and epithelial cells secured over the lens body. The epithelial cells of the appliance may be derived from cultured cells, including stem cells, such as limbal stem cells, or epithelial cell lines, or may include at least a portion of the epithelium of the eye on which the appliance is placed. The corneal appliance may have a cellular attachment element between the lens body and the epithelial cells to facilitate attachment of the epithelial cells over the lens body. The corneal appliance is intended to be used on a deepithelialized eye, which may be an eye that has had the epithelium fully or partially removed. The corneal appliance may be used to improve vision. Methods of producing the corneal appliance and of improving vision are also disclosed.~~

Remarks

Introduction

Claims 55-108, 112, 113, 118, 121-130, 132, 134-137, 139-141, 150, and 160-177 were pending, and claims 81-108, 112, 113, 118, 121-130, 132, 134-137, 139-141, 150, and 160-177 are under examination. By way of this response, the title and abstract have been amended to be more clearly directed to the presently claimed invention; claims 81, 82, 84-86, 89, 90, 94, 95, 97, 105-107, 121, 123, and 160 have been amended; claims 55-80, 87-88, 93, 118, 139, 141, 172, and 174-176 have been cancelled without prejudice; and claims 178-211 have been added. Support for the amendments to the specification and the claims can be found in the application as originally filed, and care has been taken to avoid introducing new matter. In addition, as discussed herein, support for the present amendments and new claims can be found in the priority application, U.S. App. No. 60/410,837, filed September 13, 2002.

Referring to the present application (U.S. App. No. 10/661,400) support for the amendments to claim 81 and new claim 194 can be found at least at page 39, line 16 to page 40, line 32; and page 42, lines 25-26. Support for new claims 178, 179, 197, and 198 can be found at least at page 36, line 10. Support for new claims 180 and 194 can be found at least at page 36, lines 3-4. Support for new claims 181, 182, 199, and 200 can be found at least at page 36, lines 25-28. Support for new claims 183, 184, 209, and 210 can be found at least at page 29, line 31 to page 31, line 12. Support for new claims 185-190 and 202-208 can be found at least at page 19, line 18 to page 24, line 10. Support for new claims 191-193, and 201 can be found at least at page 44, line 10 to page 45, line 6. Support for new claim 195 can be found at least at page 36, lines 3-4. Support for new claim 196 can be found at least at page 35, lines 24-27. Support for new claim 211 can be found at least at claim 107.

Amendments to claims 82, 84, 85, 86, 89, 90, 94, 95, 97, 105-107, 121, 123, and 160 have been made to read more clearly and consistently in view of the amendments to claim 81. Applicant submits no new matter has been added.

In view of the amendments presented herein, claims 81-86, 89-92, 94-108, 112, 113, 121-130, 132, 134-137, 140, 150, 160-171, 173, and 177-211 are pending.

Applicant respectfully requests entry of this Amendment and reconsideration of the objections and rejections.

Priority Date

The Office Action indicates that the provisional applications for which the present application claims the benefit of earlier filing dates have been reviewed, and that the Examiner is of the opinion that the claims have an effective filing date of September 12, 2003.

Applicant respectfully disagrees that the effective filing date is September 12, 2003. Applicant submits that the subject matter of the present independent claims and many, if not all, of the dependent claims, is described at least in U.S. App. No. 60/410,837, filed September 13, 2002, as discussed below. Therefore, applicant submits that the present claims have an effective filing date of September 13, 2002.

For example, in reference to the September 13, 2002 provisional patent application (U.S. App. No. 60/410,837), support for the subject matter of claims 81, and 194-196 can be found at least at page 25, lines 11-14; page 22, lines 15-17; page 6, lines 9-18; and page 25, lines 22-26. Support for the subject matter of claim 82 can be found at least at page 21, lines 20-31 and page 25, lines 1-20. Support for the subject matter of claims 89, 90, 185-190 and 202-208 can be found at least at page 9, line 31 to page 13, line 26. Support for the subject matter of claims 107 and 211 can be found at least at page 21, lines 29. Support for the subject matter of claim 178-180 and 197-198 can be found at least at page 22, lines 9-17 and line 23. Support for the subject matter of claim 181, 182, 199, and 200 can be found at least at page 23, lines 3-6. Support for the subject matter of claims 183 and 209 can be found at least at page 16, line 18 to page 17, line 32. Support for the subject matter of claims 184 and 210 can be found at least at page 17, lines 21-29.

In view of the above, applicant submits that the present claims, including the present independent claims 81 and 194, are properly supported in the provisional application (U.S. App. No. 60/410,837) filed September 13, 2002. Therefore, applicant submits that the present application, including the present claims, has an effective filing date of September 13, 2002.

As discussed herein, U.S. Publication No. 2003/0220653 (hereinafter Perez '653) is not prior art to the presently claimed subject matter since Perez '653 was filed on January 17, 2003 (i.e., after the effective filing date of the presently claimed invention) as a continuation-in-part application of PCT/US01/22633, filed July 18, 2001. Perez '653 introduced new matter, including formation of corneal epithelial pockets and use of synthetic materials for the lens, on

January 17, 2003, that is after the effective filing date of the presently claimed invention. Therefore, Perez '653 is not prior art to the presently claimed invention.

Specification Objections

The abstract and title were objected for allegedly not being directed to the presently claimed invention.

Applicant has amended the abstract and title as set forth above, and applicant submits the present abstract and title are more clearly directed to the presently claimed invention.

In view of the above, applicant submits that the objections to the specification have been overcome.

Claim Objection

Claim 84 was objected for not providing antecedent basis for the phrase "the lens body".

Claim 84 has been amended by deleting the word "body", and applicant submits that proper antecedence is provided for the subject matter of claim 84.

In view of the above, applicant submits that the objection to the claims have been overcome.

Rejection Under 35 U.S.C. § 102

Claims 81-84, 87-95, 97, 105, 106, 108, and 118 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,964,748 (hereinafter Peyman '748).

Applicant traverses the rejection as it relates to the present claims.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (Emphasis added; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Applicant submits that Peyman '748 does not describe each and every element set forth in the present claims, and therefore, the present claims are not anticipated by Peyman '748.

Peyman '748 discloses methods which include procedures for acting on intrastromal regions of an eye. The pockets disclosed by Peyman '748 are intrastromal pockets, and not corneal epithelial pockets. For example, Peyman '748 discloses that the created pockets are in

the stroma of the eye, see column 12, lines 43-44; column 12, lines 49-55; column 15, lines 51-53; and column 23, lines 46-48. Peyman '748 only discloses forming incisions or pockets in beneath Bowman's membrane, that is in the stroma of the cornea of an eye. For example, Peyman '748 discloses that the cut tissue has a thickness of about 0.2 mm (i.e., 200 micrometers), which is substantially greater than the thickness of the corneal epithelium (a normal human corneal epithelium has a thickness of only about 50 micrometers). Intrastromal incisions and procedures are described at least at column 9, lines 41-43; column 13, lines 30-32; column 13, lines 57-58; column 14, line 15; column 18, line 25 and line 49; column 19, lines 58-59; column 23, line 24, and lines 43-48; and column 26, line 13. Furthermore, Peyman '748 actually discloses not disturbing the corneal epithelium laying over Bowman's membrane since Peyman '748 states that the methods prevent "rupturing the descemet or Bowman's membrane" (column 12, lines 54-55; column 14, lines 13-14; and column 18, lines 47-48).

Peyman '748 does not disclose, teach, or even suggest any method that comprises a step of inserting a lens into a pocket created between a corneal epithelium of an eye and Bowman's membrane of the eye, as recited in present independent claims 81 and 194. As discussed above, Peyman '748 only discloses intrastromal pockets, which are different and distinct from corneal epithelial pockets created in the presently claimed methods. Thus, Peyman '748 does not disclose, teach, or even suggest each and every element recited in the present independent claims, and the claims dependent therefrom.

In view of the above, applicant submits that the present claims are not anticipated by Peyman '748 under 35 U.S.C. § 102.

Rejections Under 35 U.S.C. § 103

Claims 96, 100-102, and 150 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peyman '748 in view of U.S. Patent No. 4,959,353 (hereinafter Brown '353). Claim 98 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peyman '748 in view of U.S. Patent No. 6,880,558 (hereinafter Perez '558). Claims 99, 121-123, 126, 132, 139, 140, 141, 160, 163, 165, 166, 172, 173, 175, and 176 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peyman '748 in view of U.S. Patent No. 6,335,006 (hereinafter Miller '006). Claims 112, 113, 124, 125, 134-137, 161, and 162 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peyman '748, in view of Miller '006, and further in

view of Perez '653 (discussed above). Claim 164 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peyman '748 in view of Miller '006 in view of Perez '558. Claims 171 and 174 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peyman '748 in view of Miller '006 and further in view of U.S. Publication No. 2004/0015234 (hereinafter Peyman '234). Claim 177 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peyman '748 in view of Miller '006, and further in view of U.S. Patent No. 4,959,353 (hereinafter Brown '353).

Applicant traverses the rejection as it relates to the present claims.

Applicant submits that the present claims are unobvious from and patentable over the prior art, including the cited references, since the cited prior art references, taken alone or in any combination, do not disclose, teach, or suggest all of the elements recited in the present claims.

As a preliminary matter, and as discussed herein, applicant submits that Perez '653 is **not prior art** to the presently claimed invention. Therefore, Perez '653 cannot be properly used to reject the present claims. For example, as discussed above, the subject matter of at least the present independent claims is described in U.S. Application No. 60/410,837, filed September 13, 2002, and therefore, the present claims have an **effective filing date of September 13, 2002**.

In contrast, Perez '653 was filed on January 17, 2003, **after the effective filing date** of the presently claimed invention. Perez '653 was filed as a continuation-in-part of International Application No. PCT/US01/22633, and therefore, Perez '653 includes new matter relative to International Application No. PCT/US01/22633. Among the new matter that was added on January 17, 2003 by way of Perez '653 is the creation of corneal epithelial pockets and corneal onlay lenses which include synthetic materials.

For the Examiner's reference, Perez '558 (also cited in the Office Action) was filed as a continuation application of International Application No. PCT/US01/22633. Therefore, the specification and description of the invention of Perez '558 is identical to that present in International Application No. PCT/US01/22633. Perez '558 does not disclose, teach, or even suggest creating corneal epithelial pockets or pockets located between the corneal epithelium and Bowman's membrane, or lenses which are formed of non-donor corneal tissue.

Thus, applicant submits that the disclosure of Perez '653 regarding creating corneal epithelial pockets and use of non-donor corneal tissue lenses was only added on January 17, 2003, that is **after the effective filing date of the presently claimed subject matter**. Therefore,

Perez '653 is not prior art to the presently claimed invention, and any rejection of the present claims over Perez '653 cannot be properly maintained.

Regarding the rejections over the other cited references, applicant submits that the cited references, taken alone or in any combination, do not disclose, teach, or suggest each of the elements recited in the present claims, including the present independent claims.

The primary reference, Peyman '748, has been discussed above. In summary, Peyman '748 discloses insertion of ocular devices within the stroma of a cornea of an eye. The stroma is located between Bowman's membrane and the descemet membrane. Peyman '748 does not disclose, teach, or even suggest any method that comprises inserting a lens into a pocket created between the corneal epithelium of an eye and Bowman's membrane, as recited in the present claims. In addition, Peyman '748 actually teaches away from the presently claimed invention since Peyman '748 specifically states that the methods prevent interrupting or rupturing the Bowman's membrane (column 12, lines 54-55; column 14, lines 13-14; and column 18, lines 47-48) and that the cut corneal tissue has a thickness of about 200 micrometers, which is about 4x greater than the thickness of the corneal epithelium (column 9, lines 41-43).

Brown '353 discloses applying human Epithelial Growth Factor (hEGF) to an eye to promote corneal healing. Brown '353 fails to provide the deficiencies apparent in Peyman '748. For example, Brown '353 does not disclose, teach, or even suggest any pocket created in the cornea of an eye, let alone a corneal epithelial pocket. Furthermore, Brown '353 does not disclose, teach, or even suggest inserting a lens into a pocket created between the corneal epithelium and Bowman's membrane, as recited in the present claims.

Perez '558 discloses inserting an ocular device formed of donor corneal tissue under a corneal epithelial flap (see FIG. 5 and column 10, lines 51-53). Perez '558 fails to provide the deficiencies apparent in Peyman '748. For example, Perez '558 does not disclose, teach, or even suggest any pocket created in the cornea of an eye, let alone a corneal epithelial pocket. Furthermore, Perez '558 does not disclose, teach, or even suggest inserting a lens into a pocket created between the corneal epithelium and Bowman's membrane, as recited in the present claims. Furthermore, Perez '558 does not disclose ocular devices that comprise non-donor corneal tissue, as encompassed by at least claims 89, 90, 186-188, and 203-206.

Miller '006 discloses an epithelial loosening solution that contains one or more enzymes applied to the eye to facilitate delamination of the corneal epithelium. Miller '006 fails to

provide the deficiencies apparent in Peyman '748. For example, Miller '006 does not disclose, teach, or even suggest any pocket created in the cornea of an eye, let alone a corneal epithelial pocket. Furthermore, Miller '006 does not disclose, teach, or even suggest inserting a lens into a pocket created between the corneal epithelium and Bowman's membrane, as recited in the present claims.

Peyman '234 discloses placement of a corneal inlay (i.e., a lens placed in the stroma of the eye) that is placed under an epithelial flap (paragraph [0054]). In addition, Peyman '234 discloses heating the alcohol solution to help loosen the corneal epithelium (paragraph [0055]). Peyman '234 fails to provide the deficiencies apparent in Peyman '748. For example, Peyman '234 does not disclose, teach, or even suggest any pocket created in the cornea of an eye, let alone a corneal epithelial pocket. Furthermore, Peyman '234 does not disclose, teach, or even suggest inserting a lens into a pocket created between the corneal epithelium and Bowman's membrane, as recited in the present claims. In addition, Peyman '234 discloses heating the epithelium instead of cooling the corneal epithelium, as recited in claims 180 and 194. Therefore, Peyman '234 actually teaches away from at least claims 180 and 194.

Thus, applicant submits that none of the cited references, other than Perez '653, disclose, teach, or suggest all of the elements recited in the present claims. As discussed above, Perez '653 is not prior art to the presently claimed invention. For example, none of the references, other than Perez '653, disclose creating a pocket between the corneal epithelium of an eye and Bowman's membrane, let alone inserting a lens into such a pocket, as recited in the present independent claims 81 and 194. Since the references, taken alone or in any combination do not disclose, teach, or suggest all of the elements recited in the present claims, the present claims are unobvious over the cited references.

In addition, applicant submits that the prior art, as evidenced by the cited references, actually teaches away from the presently claimed invention. For example, the primary reference, Peyman '748 actually teaches away from the presently claimed invention since Peyman '748 specifically states that the methods prevent interrupting or rupturing the Bowman's membrane (column 12, lines 54-55; column 14, lines 13-14; and column 18, lines 47-48) and that the cut corneal tissue has a thickness of about 200 micrometers, which is about 4x greater than the thickness of the corneal epithelium (column 9, lines 41-43). Applicant submits that given the teachings of the cited references, a person of ordinary skill in the art would not be motivated to

combine the deficient teachings to obtain the presently claimed invention. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)).

In view of the above, applicant submits that the present claims are unobvious from and patentable over the cited references, including Peyman '748; Brown '353; Perez '558; Miller '006; Perez '653; and Peyman '234, taken alone or in any combination under 35 U.S.C. § 103.

Double Patenting

Claims 81-83, 86, 87, 89, 90, 96, and 108 have been provisionally rejected on the ground of obviousness-type double patenting over claims 1, 2, 5, 8-11, 13, and 16 of U.S. App. No. 11/183,191 in view of U.S. Patent No. 5,300,118 (hereinafter Silverstrini '118).

Applicant submits that the present claims are unobvious over the claims of U.S. App. No. 11/183,191 taken alone or in view of Silverstrini '118. For example, U.S. App. No. 11/183,191 includes claims directed to devices placed in intrastromal pockets, and not pockets created between the corneal epithelium and Bowman's membrane, as recited in the present claims. Silverstrini '118 discloses intrastromal rings placed in the stroma of an eye below Bowman's membrane. Applicant submits that the present claims, which recite inserting a lens into a pocket created between the corneal epithelium and Bowman's membrane, are unobvious from the claims of U.S. App. No. 11/183,191 taken alone or in any combination with Silverstrini '118.

In addition, applicant submits that U.S. App. No. 11/183,191 was filed on July 14, 2005 (i.e., several years after the filing date and priority date of the present application). Therefore, a patent issuing from the present application would not extend the term of the "right to exclude" for a patent issuing from U.S. App. No. 11/183,191.

In view of the above, applicant submits that the present claims are not subject to obviousness-type double patenting, and applicant requests that the provisional rejection be withdrawn.

Allowable Subject Matter

Claims 103, 104, 127-130, and 167-170 have been indicated to include allowable subject matter.

Applicant submits that each of the present claims, including independent claims 81 and 194, includes allowable subject matter. Applicant reserves the right to pursue the subject matter of original claims 103, 104, 127-130, and 167-170 as desired.

Request for listing of copending applications

The Examiner has requested a listing of copending applications that set forth similar subject matter to the present claims. Applicant assumes that the Examiner is requesting a listing of applications for which the present applicant has filed.

The following applications may describe subject matter that is similar to the present claims:

11/128,824, filed May 13, 2005
11/203,685, filed August 12, 2005
11/183,191, filed July 14, 2005 (discussed herein)
60/671,819, filed April 15, 2005
60/771,668, filed February 8, 2006

The undersigned believes that each of the above-identified applications (filed after the present application) is stored in image format in the IFW system. To the extent that one or more of these applications is not available to the Examiner, applicant respectfully requests the Examiner to telephone the undersigned at the number below to address this matter.

Conclusion

In view of the foregoing amendments and remarks, applicant submits that the present specification and claims are in proper form, and that the present claims are not subject to double patenting, and are patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 81-86, 89-92, 94-108, 112, 113, 121-130, 132, 134-137, 140, 150, 160-171, 173, and 177-211, are in condition for allowance. Notice of which is respectfully requested. If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

Date: May 3, 2006

/Greg S. Hollrigel, Reg. # 45374/

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